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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/942,563 08/31/2001 Masatoshi Narahara HIRA.0019 7597 **EXAMINER** 7590 10/29/2003 Stanley P. Fisher GOLDBERG, JEANINE ANNE Reed Smith Hazel & Thomas LLP ART UNIT PAPER NUMBER **Suite 1400** 3110 Fairview Park Drive 1634 Falls Church, VA 22042-4503

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s	5)	
	09/942,563	NARAHARA	NARAHARA ET AL.	
Office Action Summary	Examiner	Art Unit		
	Jeanine A Goldbe	<del></del>		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address P riod for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status				
1) Responsive to communication(s) filed on <u>04 September 2003</u> .				
2a)⊠ This action is <b>FINAL</b> . 2b)□ 1	This action is non-fin	al.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims				
4) Claim(s) 8 and 9 is/are pending in the application.				
4a) Of the above claim(s) is/are withdrawn from consideration.				
5) Claim(s) is/are allowed.				
6)⊠ Claim(s) <u>8 and 9</u> is/are rejected.				
7) Claim(s) is/are objected to.				
8) Claim(s) are subject to restriction and/or election requirement.				
Application Papers				
9) The specification is objected to by the Examiner.				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.				
If approved, corrected drawings are required in reply to this Office action.				
12) The oath or declaration is objected to by the Examiner.				
Priority under 35 U.S.C. §§ 119 and 120				
13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).				
a)⊠ All b)□ Some * c)□ None of:				
1.⊠ Certified copies of the priority documents have been received.				
2. Certified copies of the priority documents have been received in Application No				
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).				
a) ☐ The translation of the foreign language provisional application has been received.  15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.				
Attachment(s)				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s	5) 🔲	Interview Summary (PTO-413) P Notice of Informal Patent Applica Other:		

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#### **DETAILED ACTION**

1. This action is in response to the papers filed September 4, 2003. Currently, claims 8-9 are pending.

- 2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
- 3. Any objections and rejections not reiterated below are hereby withdrawn.

## **Priority**

4. This application claims priority to foreign filed Japanese application 2001/001761, filed January 9, 2001.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

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#### **Drawings**

5. The drawings are approved.

#### New Grounds of Rejection Necessitated by Amendment

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 6. Claims 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Chrisey et al (US Pat. 5,688,642, November 1997).

The instant claims are drawn to nucleic acid array products. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. In contrast to the instant claims, methods of making an array would be patentably distinct.

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Chrisey et al. (herein referred to as Chrisey) teaches a method of selective attachment of nucleic acid molecules to patterned self-assembled surfaces. As seen in Figure 5, a substrate is coated with a coating of a silane that is resistant to the binding of nucleic acid oligomers. The UV light selectively removes the non-DNA -binding silane and leaves a hydroxylated surface on the substrate. The amino terminus is available for covalently binding DNA oligomers. Chrisey teaches that the crosslinking agents are typically thiols. Thiol reactive groups include malemides (col. 8, lines5-10). Chrisey teaches covalent immobilization using aminosilane films modified with a heterobifunctional crosslinker and thiol-modified DNA oligomers (col. 14-15). Chrisey teaches EDA and DETA films were prepared on silica slides. A solution of SMPB (succinimidyl 4-(p-maleimodophenyl)butyrate was and used to treat the slides (col. 15, lines 5-10). Slides were rinsed and transferred to a jar with DNA oligomer. The slides were rinsed in water. To remove non-covalently bound DNA from the slides the slides were further washed. As seen in Figure 3, a covalent bond exists between the probes and a maleimide group (limitations of Claim 9).

#### **Response to Arguments**

The response traverses the rejection. The response asserts that Chrisey applies PHMG to the slides before any probes are immobilized by covalent bonds. This argument has been reviewed but is not convincing because the resulting product is identical. The product which places the probes on first and the product which places the probes on after maleimide groups, does not differ in structure. Thus, the same product would be generated regardless of the order of the placement.

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The response has amended the claims to recited "on the substrate surface where no nucleic acid probe is previously immobilized by covalent bonds." This argument has been thoroughly reviewed, but is not found persuasive because the maleimides are placed in locations where no nucleic acid probe has been previously immobilized, as no probes have been previously immobilized.

Thus for the reasons above and those already of record, the rejection is maintained.

#### Conclusion

- 7. No claims allowable over the art.
- 8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg October 28, 2003

> BJ FORMAN, PH.D. PRIMARY EXAMINER